

Patent Application Serial No. 09/740,191

**REMARKS**

The Final Office Action mailed September 3, 2002 (hereinafter the Office Action), has been received and reviewed. Claims 12 through 24 are currently pending in the application, and claims 12 through 24 stand finally rejected. Applicants, however, respectfully request reconsideration of the application in light of the remarks set forth herein.

**Double Patenting**

Applicants note with appreciation the withdrawal of the double patenting rejection of claim 1.

**Rejections Under 35 U.S.C. § 102**

Claims 12, 14, 17, 18, 20, and 23 stand finally rejected under 35 U.S.C. § 102(b) (hereinafter "Section 102(b)") as being anticipated by Eckenhoff et al. (U.S. Patent 4,663,148). However, in order for a reference to anticipate a claim under Section 102(b) that references must expressly or inherently set forth each and every element recited in the claim. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Eckenhoff et al. fails to expressly or inherently teach each and every limitation recited in the rejected claims. In particular, Eckenhoff et al. fails to expressly or inherently teach a dosage form comprising a self-emulsifying drug formulation. Therefore, Applicants respectfully submit that the teachings of Eckenhoff et al. do not anticipate claims 12, 14, 17, 18, 20, and 23, and Applicants respectfully request that the rejection of claims 12, 14, 17, 18, 20, and 23 under Section 102(b) be withdrawn.

With respect to the teachings of Eckenhoff et al., it is stated at page 3 of the Office Action that the reference teaches a dispenser for delivering a temperature-sensitive beneficial drug formulation, wherein the drug formulation includes a butter, wax, stearate, hydrogenated oil, partially hydrogenated oil, glyceride, glycol, ester or polyether. It is further stated at page 3 that "[t]he ingredients that make up the temperature sensitive means, which include surfactants and mono- and di-glycerides . . .," meet the limitations of claims 12, 14, 17, 18, 20, and 23. However, Applicants respectfully emphasize that each of the claims pending in the present application recite a dosage form comprising a self-emulsifying formulation, and Applicants respectfully submit that the teaching that

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a temperature-sensitive drug formulation can be created using surfactants and mono- and diglycerides does not anticipate the subject matter recited in the pending claims.

It is easily understood that simply because a reference discloses materials that could be used to create a composition, it does not follow that such a reference teaches the composition itself. Therefore, even if the formulation materials taught in Eckenhoff et al. could be used to create a self-emulsifying composition, the teachings of Eckenhoff et al. can not anticipate the claims presently pending unless Eckenhoff et al. actually teaches the combination of such formulation materials to achieve a self-emulsifying formulation. However, the teachings of Eckenhoff et al. are directed to dosage forms including thermo-responsive drug formulations, and Applicants respectfully submit that Eckenhoff et al. does not teach or even contemplate that the formulation materials taught therein could be combined to achieve a self-emulsifying drug formulation. Therefore, Eckenhoff et al. does not anticipate any of claims 12, 14, 17, 18, 20, and 23 and the rejection of such claims under Section 102(b) should be withdrawn.

Claims 12 through 23 are also finally rejected in the Office Action under Section 102(b) as being anticipated by Wong et al. (U.S. Patent 5,324,280). However, Applicants respectfully submit that Wong et al. fails to expressly or inherently teach each and every limitation recited in the rejected claims. Like Eckenhoff et al., Wong et al. fails to expressly or inherently teach a dosage form comprising a self-emulsifying drug formulation. Therefore, Applicants respectfully submit that the teachings of Wong et al. do not anticipate claims 12 through 23, and Applicants respectfully request that the rejection of claims 12 through 23 under Section 102(b) be withdrawn.

Regarding the teachings of Wong et al., it is asserted in the Office Action that the reference discloses "the ingredients that make up the beneficial agent liquid formulation," and various columns and line numbers from Wong et al. are referenced. *See, Office Action*, page 4. It is further asserted that such teachings "meet the limitations of applicants' claims 12, 14, 16-18, 20, 22, and 23." *See, Id.* However, such assertions overlook the limitations found in presently pending claims. Again, each of the pending claims recites a dosage form that includes a self-emulsifying drug formulation. The simple fact that Wong et al. may teach materials or "ingredients" that could be used to create a self-emulsifying drug formulation does not amount to anticipation of the rejected claims under

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Section 102(b). In order for Wong et al. to anticipate any of claims 12, 14, 16-18, 20, 22, and 23 under Section 102(b), the reference must actually teach the combination of the materials to achieve a self-emulsifying formulation. The teachings of Wong et al. are directed to a dosage form for delivery of a liquid formulation, but, as is true of the teachings found in Eckenhoff et al., the teachings of Wong et al. do not teach or even contemplate that the formulation materials disclosed therein could be combined to achieve a self-emulsifying formulation. Therefore, Wong et al. does not anticipate any of claims 12, 14, 16-18, 20, 22, or 23, and the rejection of such claims under Section 102(b) should be withdrawn.

If it is the Examiner's assertion that the teachings of Eckenhoff et al. and Wong et al. inherently anticipate the claims pending in the present application, then it is the Examiner's burden to provide evidence "that must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art." See, *M.P.E.P.*, § 2112, p. 2100-51. In other words, "[i]n relying on the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See, *M.P.E.P.*, § 2112, p. 2100-52, *emphasis in original*. Significantly, "[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." See, *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). In this case, neither Eckenhoff et al. nor Wong et al. teaches a dosage form including a self-emulsifying formulation. Therefore, in order for the Examiner to properly establish that either of these two references inherently anticipates the rejected claims, the Examiner bears the burden of providing a basis in fact and/or technical reasoning that establishes that each time the formulation components of Eckenhoff et al. or Wong et al. are brought together, a self-emulsifying drug formulation necessarily results. Applicants respectfully submit that such a burden has not been met.

Applicants respectfully note that the Office Action provides no basis in fact or technical reasoning that reasonably supports a determination that the subject matter recited in the rejected claims necessarily flows from the teachings of either of the cited references. As it is used in the

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present application, the term "emulsion" defines a two-phase system in which one phase is finely dispersed in the other phase. *See, Specification*, page 4. And a self-emulsifying formulation according to the present invention is a formulation that itself is not an emulsion but forms and emulsion *in-situ* upon delivery to an environment of operation. *See, Specification*, page 2 and Examples 1 through 5. Applicants respectfully note oils do not generally form a finely dispersed two-phase system upon contact with an aqueous phase. Instead, an oil introduced into an aqueous phase will generally separate from the aqueous phase in bulk, creating a two phase system wherein the oil phase is not miscible with or dispersed within the aqueous phase. Moreover, the simple fact that a composition includes surfactant and oil does not mean that such a composition will self-emulsify upon introduction into an aqueous phase. The Office Action provides no facts or technical reasoning that establish that persons of ordinary skill in the art would recognize a dosage form including a self-emulsifying formulation necessarily flows from the teachings of Eckenhoff et al. or Wong et al. Thus, Applicants respectfully submit that if it is to be argued that either Eckenhoff et al. or Wong et al. inherently teach a dosage form comprising a self-emulsifying formulation, the burden of establishing a reasonable basis for such a conclusion remains with the Examiner.

### 35 U.S.C. § 103(a) Obviousness Rejections

Pending claims 12 through 24 are finally rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over either Eckenhoff et al. or Wong et al. However, a rejection under Section 103(a) is improper and will be overturned unless a *prima facie* case of obviousness is established against the rejected claims. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). Applicants respectfully submit that neither of the references cited in the Office Action provides evidence sufficient to properly establish the *prima facie* obviousness of any of claims 12 through 24. Thus, Applicants respectfully request that the rejections of claims 12 through 24 under Section 103 be withdrawn.

As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 can not be established unless three criteria are met:

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First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

It is the examiner that bears the burden of establishing these three criteria through the application of objective teachings or knowledge. *See, M.P.E.P.* § 2142.

In the instant application, Applicants respectfully submit that, when taken individually or in combination, Eckenhoff et al. and Wong et al. fail to teach or suggest each of the limitations recited in any of the rejected claims. As has already been discussed, each of the claims pending in the present application recite a dosage form that includes a self-emulsifying drug formulation. However, the teachings of Eckenhoff et al. and Wong et al. do not teach or suggest a dosage form comprising a self-emulsifying formulation. Therefore, these two references do not serve to establish the *prima facie* obviousness of any of the rejected claims.

Claims 12, 14, 17, 18, 20 and 23 are rejected in the Office Action under Section 103 as being unpatentable over Eckenhoff et al. It is noted in the Office Action that Eckenhoff et al. teaches a dispenser that includes a temperature sensitive drug composition. It is first asserted in the Office Action that "[t]he ingredients that make up the temperature-sensitive means includes surfactants and mono- and di-glycerides. . . ." *See, Office Action*, page 6. Next it is asserted that, based on the teachings of Eckenhoff et al., "it would have been obvious for one of ordinary skill in the pharmaceutical art at the time the invention was made to formulate a dispenser containing a beneficial drug composition into the environment," and that the expected result of such an activity would be "a thermo-responsive, hydrophobic composition comprising insoluble to soluble drugs . . . ." *See, Office Action*, page 6. However, such assertions and conclusions do not speak to the limitations recited in the rejected claims. Claims 12, 14, 17, 18, 20 and 23 are directed to dosage forms comprising a self-emulsifying formulation, and though a self-emulsifying formulation may be formulated to be temperature sensitive, a temperature sensitive formulation is not necessarily self-

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emulsifying. Applicants respectfully emphasize that the teachings of Eckenhoff et al. fail to teach or suggest a self-emulsifying drug formulation or a dosage form containing such a formulation, and the Office Action includes no evidence that supports a conclusion that teaching various materials suitable for forming a thermo-responsive drug formulation obviates the invention of a dosage form comprising a self-emulsifying formulation. Applicants, therefore, respectfully submit that the teachings of Eckenhoff et al. do not establish the *prima facie* obviousness of claims 12, 14, 17, 18, 20 and 23, and Applicants respectfully request that the rejection of such claims under Section 103 be withdrawn.

Applicants further submit that the teachings of Wong et al. do not establish the *prima facie* obviousness of claims 12 through 24 and request that the rejection of claims 12 through 24 under Section 103 as unpatentable in light of Wong et al. be withdrawn. It is noted at page 6 of the Office Action that "[t]he osmotic system [of Wong et al.] comprises: (a) a capsule; (b) a dosage amount of a beneficial agent liquid formulation; (c) an osmagent composition; (d) a semi-permeable composition; (e) at least one orifice that communicates with the exterior and the lumen." It is then immediately concluded that it would have, therefore, "been obvious to one of ordinary skill in the art at the time the invention was made to formulate an osmotic system for delivering at a controlled rate, a beneficial formulation to a fluid environment of use based on the teachings of Wong." Page 6 of the Office Action concludes with a final assertion that "the expected result" of fabricating such a dosage form "would be an osmotic system manufactured in the form of an osmotic device for delivering in vivo a beneficial liquid drug formulation, such as a lipophilic drug formulation that is difficult to deliver." Yet, such reasoning and assertions again fail to address the limitations recited in each of claims 12 through 24, which recite dosage forms that include a self-emulsifying formulation. The teachings of Wong et al. do not teach or suggest such a dosage form including a self-emulsifying formulation, and Applicants respectfully submit that the Office Action provides no evidence to support a different conclusion. Because Wong et al. does not teach or suggest each and every limitation recited in claims 12 through 24, the reference cannot establish the *prima facie* obviousness of these claims, and the rejection of claims 12 through 24 under Section 103 should be withdrawn.

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**CONCLUSION**

Claims 12 through 24 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, she is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,



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Date: March 3, 2003